

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

PAMELA BUTLER, et al.,)
v.)
Plaintiffs,) Case No. 4:18-cv-01701-AGF
v.)
MALLINCKRODT LLC, et al.) Lead Case
Defendants.)
ORAL ARGUMENT REQUESTED

DEFENDANTS' JOINT REPLY IN SUPPORT OF THEIR JOINT MOTION TO EXCLUDE THE TESTIMONY OF PLAINTIFFS' EXPERT HOWARD HU, M.D.

Defendants Mallinckrodt LLC (“Mallinckrodt”) and Cotter Corporation (N.S.L.) (“Cotter”) file this Joint Reply in Support of Their Joint Motion to Exclude the Testimony of Plaintiffs’ Expert Howard Hu, M.D. (Doc. #51).

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I. INTRODUCTION

Dr. Hu’s opinion that Dr. Clark’s manufactured doses of ionizing radiation caused these Plaintiffs’ cancer is not based on a reliable methodology. To put Dr. Clark’s doses into context, the ATSDR Report—which Dr. Hu relied on—incorporated a Minimum Risk Level (“MRL”) of 100 millirem per year, which it defined as a dose so low that “no harmful effects have been shown to be associated with” it. Here, Dr. Clark admitted that all of the doses to be used in Dr. Hu’s causation opinion were below this MRL. As a result, the ATSDR Report would conclude there are “no harmful effects” from Dr. Clark’s doses, and yet Dr. Hu concluded those same doses caused these Plaintiffs’ cancers.

Dr. Hu’s unreliable methodology results from his attempts to wrestle these insignificant doses into a finding of specific causation. In addition to contradicting his primary source, Dr. Hu also ignored accepted science and obvious errors in Dr. Clark’s work, further undermining the reliability of his ultimate conclusions. In essence, Dr. Hu opines that any dose of ionizing radiation *can* cause cancer and—without more—that it did in fact cause these Plaintiffs’ cancer. Tellingly, he admits there is nothing that could have happened to Plaintiffs that would change that opinion.

Dr. Hu’s failure to support his opinion is on full display in Plaintiffs’ Opposition (Doc. #70), which rarely cites to his testimony or reports. Instead of showing this Court that Dr. Hu’s opinions are admissible through Dr. Hu’s testimony or reports, Plaintiffs spend pages arguing what Dr. Hu did without citing to any support, while ignoring all contradictory authority. Defendants urge the Court to exclude Dr. Hu’s opinion in its entirety for any of the reasons set forth in Defendants’ Motion (Doc. #51).

II. STANDARD OF REVIEW

Plaintiffs do not dispute that they bear the burden of establishing the admissibility of Dr. Hu’s testimony. *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757–58 (8th Cir. 2006).

Plaintiffs wrongly portray the Eighth Circuit as an open door to unsupported testimony. In fact, the Eighth Circuit follows Supreme Court precedent that, under *Daubert*, the “district court’s gatekeeping role separates expert opinion evidence based on ‘good grounds’ from subjective speculation that masquerades as scientific knowledge.” *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001). In other words, before admitting expert testimony, “the trial court must make ‘a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.’” *Polski v. Quigley Corp.*, 538 F.3d 836, 838 (8th Cir. 2008) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592–93 (1993)). Under this two-fold analysis, “[e]ven a theory that might meet certain *Daubert* factors, such as peer review and publication, testing, known or potential error rate, and general acceptance, should not be admitted if it does not apply to the specific facts of the case.” *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1056 (8th Cir. 2000).

As Defendants’ Memorandum details, Dr. Hu’s opinions fail every single Rule 702 consideration: Dr. Hu has no scientific, technical, or other specialized knowledge that will help the trier of fact understand the evidence or determine a fact in issue, Rule 702(a); his opinion is not based on the facts or data in this case, Rule 702(b); his testimony is not the product of reliable principles or methods, Rule 702(c); and he fails to apply the principles and methods reliably to the facts of the case, Rule 702(d).

III. ARGUMENTS & AUTHORITIES

A. Dr. Hu Knew There Were Errors in Dr. Clark’s Doses and Relied on Them Anyway.

Plaintiffs do not contest the fact that if Dr. Clark’s doses are not admissible, then Dr. Hu’s specific causation opinion must also be excluded. Nor could they. Dr. Hu conceded at deposition that his opinions “are only as good as” Dr. Clark’s numbers. (Hu *Butler* 119:10–12.)¹

Instead, Plaintiffs’ primary argument for the admissibility of Dr. Hu’s testimony is that “an expert is allowed to rely on the admissible opinions of another expert.” (Doc. #70 at 11.) Critically, Dr. Clark’s opinions are not admissible. (*See* Defs.’ Mtn to Exclude Dr. Clark.) But even if Dr. Clark’s testimony were admissible, Dr. Hu’s testimony is independently inadmissible under *Daubert*. Plaintiffs do not rebut Defendants’ authority that an expert is subject to exclusion for blindly relying on the work of other experts. (Doc. #52 at 9.) By their silence, Plaintiffs concede, as Dr. Hu did in his deposition, that he did nothing to validate Dr. Clark’s work. (Doc. #52 at 9–11.) And while Plaintiffs now assert that Dr. Hu’s reference to “obvious errors” in Dr. Clark’s work referred only to typos, they offer no evidence to support this interpretation—and the testimony itself clearly refers to Dr. Clark’s substantive work. (Hu *Butler* 124:12–17.)

Even still, Plaintiffs do not contest that Dr. Hu relied on Dr. Clark’s doses *despite knowing its errors*. (Doc. #70 at 12–13). Instead, their only argument is to assert that Dr. Clark’s doses are reliable, so Dr. Hu can rely on them *ipso facto*. *Id.* The case Plaintiffs cite for this proposition is not applicable because there was no evidence in that case that the expert recognized “obvious errors” in the other expert’s work and relied on it anyway. (Doc. #70 at 14–15, citing *Johnson v. Avco Corp.*, 702 F.Supp. 2d 1093, 1102 (E.D. Mo. 2010).)

¹ Dr. Hu’s deposition is located at Doc. #52-2.

Here, Dr. Hu admitted multiple significant problems in Dr. Clark’s work. He testified it was not appropriate for Dr. Clark to use a 70-year dose to analyze causation for these Plaintiffs because they have much shorter exposure periods and *no literature* supports a 70-year dose in this case. (Doc. #52 at 9–11.) He also admitted that Dr. Clark’s doses did not account for the latency periods, and that Dr. Hu did not correct for it because he did not know how to do so. (*Id.* at 11.)

For an example of these errors, Plaintiff Pamela Butler alleges exposure to Coldwater Creek from when she was 25 to 35 years old. She was diagnosed with breast cancer at age 57. The time-period before her alleged exposure and the time-period after her diagnosis are not relevant to her doses because neither period could have contributed to causing her cancer. Further, because dose reconstructions for the cancers in this case must exclude the 10-year “latency” period—the 10-year period of time prior to diagnosis—Ms. Butler’s dose cannot include any years beyond age 47, ten years before her diagnosis. (Doc. #52 at 10–11.) As a result, the only period of time relevant to Ms. Butler’s dose reconstruction are the years from ages 25 to 47 (22 years), yet Dr. Clark utilized a 70-year dose period, adding 48 years to Ms. Butler’s dose that could not possibly have caused or contributed to her cancer. Dr. Hu nonetheless blindly accepted these doses and based his opinion on them as if they were gospel. (*Id.*) Plaintiffs’ inability to cite caselaw permitting such opinions under *Daubert* is understandable—there is none.

Dr. Hu’s recognition of such errors and his willingness to rely on the doses anyway requires exclusion. *TMI* is directly on point. In *In re TMI Litig.*, 193 F.3d 613, 715 (3d Cir. 1999), *amend.* 199 F.3d 158 (3d Cir. 2000), the expert testified that “he relied on the opinions of plaintiffs’ other dose experts and assumed the correctness of each expert’s proposition.” He then testified he had never seen others in his field perform similar analyses. *Id.* The Court excluded the expert’s opinions because he failed “to assess the validity of the opinions of the experts he relied on.” *Id.*

That fact, “together with his unblinking reliance on those experts’ opinions, demonstrate[d] that the methodology he used to formulate his opinion was flawed under *Daubert* as it was not calculated to produce reliable results.” *Id.* Contrary to Plaintiffs’ assertion, the expert was not excluded because the experts before him were excluded but because he, as Dr. Hu does here, recognized errors in the work he was relying on and relied on it anyway.

B. Dr. Hu’s Method Contradicts the Source On Which It Relies.

Despite relying exclusively on the ATSDR Report for his underlying methodology, Dr. Hu’s analysis contradicts three of its critical conclusions. (Doc. #52 at 16–17.)

First, the ATSDR report states its approach “would not be used in detailed dose reconstruction” and “the estimated exposures do not apply to individuals or even an average individual.” (*Id.*) Plaintiffs have no meaningful response to this because Dr. Hu admitted that Dr. Clark used the ATSDR methodology in the exact manner it prohibited him from doing. (*Id.*)

Second, the ATSDR report utilized a Minimum Risk Level (“MRL”)—again, a dose so low that “no harmful effects have been shown to be associated with” it—of 100 millirem *per year*. (*Id.*) Dr. Clark testified that all of the doses he calculated were below the ATSDR’s MRL. Despite this, and despite the ATSDR’s conclusion that “no harmful effects have been shown with” a dose below 100 millirem per year, Dr. Hu opined the doses in this case *caused* these Plaintiffs’ cancer.

Third, the ATSDR report, even with its overly conservative approach (discussed at Doc. #82 at Sec. III.A.2), concluded Coldwater Creek exposure did not create *any* increase in cancer risk for the cancers at issue in this case (brain, breast, mantle cell lymphoma). (Doc. #52 at 16–17.) Neither Dr. Hu nor Plaintiffs explain how Dr. Hu can conclude that ionizing radiation caused these Plaintiffs’ cancers despite the ATSDR’s ultimate conclusion. (*Id.*)

Plaintiffs offer no scientific authority or other support for their bald assertion that there was “nothing improper or unscientific” about Dr. Hu’s selective reliance on the ATSDR, but that is

exactly the type of unreliable methodology and litigation-driven approach that must be excluded under *Daubert*. *In re Accutane Prods. Liab.*, No. 8:04-MD-2523-T-30TBM, 2009 WL 2496444, at *2 (M.D. Fla. Aug. 11, 2009), *aff'd*, 378 F. App'x 929 (11th Cir. 2010); *see also In re Wholesale Grocery Prod. Antitrust Litig.*, 946 F.3d 995, 1001 (8th Cir. 2019) (“Under *Daubert*, any step that renders the analysis unreliable . . . renders the expert’s testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology” (citations and internal quotations omitted)).

C. Dr. Hu’s Own Testimony Refutes Plaintiffs’ Assertion That Dr. Hu’s Maximum Exposure Methodology Is Reliable.

Plaintiffs argue that the “Maximum” doses Dr. Hu used—in supplemental reports issued five months late—are reliable because the Plaintiffs’ “true exposures” were closer to the Maximum exposure calculated by Dr. Clark and because the EPA sometimes uses higher doses in its risk assessment work. (*Compare* Doc. #52 at 21–23 *with* Doc. #70 at 15–16.) But Plaintiffs do not cite any supporting testimony from Dr. Hu, the testimony they do cite does not support them, and Dr. Hu’s testimony itself refutes both arguments.

First, Plaintiffs argue that the Maximum doses are appropriate because the Plaintiffs “move[d] around” and were exposed to radiation at more than “one point in time or at one location.” (Doc. #70 at 15.) Yet Dr. Clark’s Maximum doses assume the opposite: they assume Plaintiffs *did not* move around and instead spent their entire exposure period simultaneously at the highest concentration locations Dr. Clark could find, and maintained this posture *for their entire exposure period*, i.e., 24/7/365. (Doc. #52 at 21–23.) Even Dr. Hu conceded this was inappropriate. (*Id.*)

Second, Plaintiffs argue their “true exposures” are on the high end of the range Dr. Clark was able to quantify because of possible additional exposures, like Plaintiff Butler’s alleged

exposure to radiation from her dog. (Doc. #70 at 16). But at the same time, Plaintiffs concede they cannot quantify these “additional exposures.” (*Id.*) Plaintiffs make no effort to explain how Drs. Clark and Hu can know that the Plaintiffs’ “true exposures” are closer to the fictional and impossible Maximum doses when the additional exposures “cannot be quantified.”

Third, Plaintiffs assert Dr. Hu should be able to rely on the Maximum doses because they claim the EPA sometimes presents higher-end doses in its analyses. But *Dr. Hu* obviously did not rely on the EPA’s (or any other agency’s) use of a Maximum dose when generating his opinion because he disclaimed any knowledge of federal agencies’ use of such doses in his deposition. (Doc. #52 at 23, citing Hu *Butler* 251:19–24.) Nor would a regulatory agency rely on doses based on a patently impossible premise. And Plaintiffs have not cited to any such agency reliance.

Finally, Dr. Hu’s other admissions regarding his reliance on these Maximum doses are equally fatal. Dr. Hu admits: (1) it is impossible for a Plaintiff to be at multiple different locations at one time as required to receive the Maximum dose; (2) there is no authoritative literature that uses this “Maximum” dose to calculate causation; (3) Dr. Hu has never used such a Maximum dose to calculate causation; (4) Dr. Hu has never seen anyone but Dr. Clark use this Maximum dose to calculate causation; (5) Dr. Hu is not qualified to choose the appropriate dose to evaluate risk; and (6) Dr. Clark, the exposure assessor, identified the RME (Reasonable Maximum Exposure)-based dose, not the “Maximum” dose, as appropriate for causation analysis. (Doc. #52 at 23.) Dr. Hu’s spontaneous switch to the Maximum doses in his late Addenda reports simply confirms that his opinions are not guided by science but by Plaintiffs’ desired litigation outcome. As such, they should be excluded. *See Castellow v. Chevron USA*, 97 F.Supp. 2d 780, 786 (S.D. Tex. 2000).

D. Plaintiffs Do Not Address Defendants' Criticisms of Dr. Hu's 1 in 1 Million Risk Threshold That Contradicts Both Dr. Clark and the ATSDR.

In addition to the Maximums, Dr. Hu's Addenda identified for the first time a causation threshold upon which Dr. Hu claimed he based his opinion. (Doc. #52 at 23.) He claimed that if a Plaintiffs' exposure increased their risk of cancer to more than 1 in 1 million, he would opine radiation caused their cancer even though he admitted that a 1 in 1 million risk is "negligible" in terms of causation. (*Id.*; Hu *Czapla* Vol. II 37:1–3; Hu *Czapla* Vol. I 63:5–15.) But even more importantly, this threshold contradicts both Dr. Clark and the ATSDR, who presented a risk threshold of 1 in 10,000. (*Id.*)

Dr. Hu could not use Dr. Clark's and the ATSDR's 1 in 10,000 risk level because doing so would result in a "no effect" finding for these Plaintiffs. (*Id.* at 24.) Not to be deterred from achieving his ultimate goal of finding causation, Dr. Hu just changed the risk level to 1 in 1 million. (*Id.*) Problem solved.

Dr. Hu's willingness to work backward from his conclusion to find scientific support "cannot withstand *Daubert* scrutiny and is not due any credence in a court of law." *Castellow*, 97 F.Supp. 2d at 786 (excluding expert for beginning "with the conclusion that [Plaintiff's] AML was caused by exposure to harmful levels of benzene . . . [and] work[ing] backward to find medical and scientific support). Plaintiffs have no response. They do not defend Dr. Hu's change of opinion, five months after his initial reports, to significantly lower the risk threshold, and they make no attempt to square it with Dr. Clark's or the ATSDR's risk threshold. Nor do they address *Castellow* or similar caselaw. Plaintiffs' silence on this point speaks volumes.

E. The "Linear No Threshold Model" Does Not Support Dr. Hu's *Specific Causation* Opinion.

Plaintiffs concede that ionizing radiation has been widely studied and that there is no epidemiology supporting Dr. Hu's causation opinion. (*Compare* Doc. #52 at 11 *with* Doc. #70 at

21.) They also do not contest Defendants' assertion that Dr. Hu failed to reliably consider epidemiology in his opinion. Instead, they claim Dr. Hu does not need epidemiology supporting his specific causation opinions because he is relying on the "linear-no-threshold" theory. Plaintiffs then undermine their own argument by citing to a case where the Eighth Circuit affirmed the exclusion of an expert *for relying on a linear-no-threshold theory for causation*. *Nat'l Bank of Com. of El Dorado v. Assoc. Milk Producers, Inc.*, 191 F.3d 858, 861 (8th Cir. 1999) (linear-no-threshold theory "has respectable scientific support but does not provide a scientific basis for a jury to find" causation by a preponderance standard).²

Plaintiffs also cite to *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929 (8th Cir. 2001), for the same proposition that Dr. Clark does not need to cite to supporting epidemiology, but *Bonner* dealt with a novel toxin-disease relationship where there was no epidemiology at all. Here, in sharp contrast, the epidemiology of radiation is well developed, with decades of extensive peer-reviewed studies. And yet Dr. Hu could not find a *single* study that supports causation for the cancers at issue based on Dr. Clark's manufactured doses.³

Dr. Hu's own testimony further undermines Plaintiffs' argument: he admitted he does not know the epidemiological relationship between cancer causation and ionizing radiation, but only knew it did not support causation at these doses. (Doc. #52 at 12–13.) Dr. Hu's ignorance of the epidemiology, particularly in light of his admission that the "dose response" relationship is

² Other courts and authorities similarly reject the linear-no-threshold theory as a basis for specific causation. *See, e.g., Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 679 (6th Cir. 2011); *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1166 (E.D. Wash. 2009); *Reference Manual on Scientific Evidence* 643 (3d ed. 2011) (although some courts accept the linear-no-threshold model in "administrative rulemaking," it "flies in the face of the toxicological law of dose-response ... doesn't satisfy *Daubert*, and doesn't stand up to scientific scrutiny" (quoting *In re W.R. Grace & Co.*, 355 B.R. 462, 476 (Bankr. D. Del. 2006))).

³ *Bonner* is also distinguishable because there the Court "emphasized that the causation opinion on the plaintiff's immediate, acute symptoms was reliable because of the temporal connection between the exposure and the symptoms"—a connection lacking here. *Marmo*, 457 F.3d at 758.

important, cannot be reliable science. (Hu *Butler* 113:25–114:2.) Even worse, Dr. Hu claimed he did rely on epidemiology to rule out other possible causes of the cancers, but he made no attempt to explain why the epidemiology for these other possible causes is an important consideration while the epidemiology for ionizing radiation is not. (Hu *Butler* 219:9–221:21.)

TMI, cited by both Parties on this issue, also undermines Plaintiffs’ argument. Plaintiffs cite *TMI* for the proposition that “[e]ven at very low doses it is possible that ionizing radiation may deposit sufficient energy into a cell to modify . . . Consequently, it is assumed that there is no threshold for the initiation of a stochastic event.” *In re TMI Litig*, 193 F.3d at 642 (citing an article co-authored by Mallinckrodt’s expert, Fred Mettler, Jr., M.D.) But Plaintiffs’ selective reliance on *TMI* makes no sense given that Defendants already quoted *TMI*’s conclusion (six paragraphs later) that “[t]he primary basis to link specific cancers with radiation exposures is data that has been collected regarding the increased frequency of malignancies following exposure to ionizing radiation . . . *In other words, causation can only be established (if at all) from epidemiological studies of populations exposed to ionizing radiation.*” (*Id.* at 643 (emphasis added).) Dr. Hu’s reliance on the linear-no-threshold theory *for his specific causation opinion* is plainly insufficient here, as he concedes the epidemiology shows no causal relationship between such low doses and the cancers at issue.

F. Plaintiffs Must Show an Exposure Above Natural Background Levels.

Plaintiffs concede they must show exposure to radiation above natural background levels. (Doc. #70 at 21.) Dr. Hu knew this: he opines Plaintiffs were exposed to “high” levels of radiation in excess of natural background. (Doc. #52 at 14.) But his methodology is not reliable because he knowingly compared Plaintiffs’ doses to fictional background levels made up by Dr. Clark. (*Id.*)

Plaintiffs do not contest that Dr. Hu relied on Dr. Clark’s fictional background numbers despite knowing that (1) Dr. Clark did not incorporate the universally accepted natural background

into his analysis, (2) he has never seen anyone use natural background the way Dr. Clark did, and (3) no scientific authority uses background in that manner. (Doc. #52 at 14–15.) Plaintiffs concede these facts but appear to argue that any dispute over background numbers should go to the jury. The only case they cite for support, however, concerned the background level of PCBs in the bloodstream, which was not a scientifically settled matter. *In re Paoli Railroad Yard PCB Litigation*, 916 F.2d 829 (3d Cir. 1990). Here, in contrast, settled case law and settled science are aligned with regard to natural background, both of which are consistent with Dr. Hu’s understanding of it.⁴ Perhaps not surprisingly, neither Dr. Clark nor Dr. Hu even attempted to justify Dr. Clark’s ridiculously low fictional background.⁵

Even after conceding they must establish exposure above background, Plaintiffs suggest—without citation—that Missouri law applies and does not require them to show exposure above background. Nonsense. *First*, Plaintiffs sued under the Price-Anderson Act. The Act’s standards apply over any inconsistent Missouri law. *Halbrook v. Mallinckrodt, LLC*, 888 F.3d 971, 975 (8th Cir. 2018). The Act “requires that plaintiffs demonstrate they have been exposed to a greater extent than anyone else, i.e., that their exposure levels exceeded the normal background level.” *In re TMI Litig.*, 193 F.3d at 659; *see also* Doc. #70 at 22, citing *McMunn*, 131 F.Supp. 3d at 399 (“Plaintiffs still must demonstrate that they were exposed to ‘this radiation’ … in excess of normal background radiation amounts. Otherwise, they cannot demonstrate causation”). *Second*, even Missouri law requires the Plaintiffs to show that ionizing radiation caused their cancer, and that means showing an exposure above background, as the cases Plaintiffs cite make clear. (Doc. #70 at 22 citing

⁴ See Doc. #82, Reply to Motion to Exclude Clark, Sec. III.C for a detailed discussion of background.

⁵ Plaintiffs assert that any exposure at all will drive a Plaintiffs’ overall exposure above background. (Doc. #70 at 22.) But Dr. Hu did not attempt to determine whether an exposure is high enough above background to be significant. *See generally Cano v. Everest Minerals Corp.*, 362 F.Supp. 2d 814 (W.D.Tex 2005) (discussing background). At minimum, comparison of the alleged exposures to natural background is a required element, as Plaintiffs concede, and Dr. Hu failed to perform it.

McMunn, 131 F.Supp. 3d at 399). *Third*, regardless of what law Plaintiffs believe they are proceeding under, Dr. Hu’s opinion still must be admissible under Rule 702. And Dr. Hu’s actual analysis as to background levels is contradicted by every scientific and legal authority. Plaintiffs do not argue otherwise. His opinion must be excluded.

G. Dr. Hu Must Do More Than Say He Performed a Differential Etiology.

Plaintiffs’ contention that Dr. Hu performed a differential etiology is pure fiction. He did not examine the Plaintiffs, he did not speak to them, and he did not review their Court-mandated questionnaires detailing their exposure, work, and residential histories. (Doc. #52 at 17–19.) Dr. Hu admits he only spent thirty minutes total reviewing the four Plaintiffs’ medical records despite having thousands of pages of medical records for use in his opinions. (*Id.*) He did not investigate, much less rule out, other obvious possible causes of these Plaintiffs’ cancers, like decades of heavy smoking or industrial pesticide use. (Doc. #52 at 19; Hu *Butler* 221:2–10, 226:24–232:19, 265:12–220; 267:5–14.)

Plaintiffs do not dispute these facts and merely assert that in the Eighth Circuit, a differential etiology is “presumptively admissible.” (Doc. #70 at 2–3.) But, as Plaintiffs acknowledge, the phrase originated in *Glastetter*, which held that “a medical opinion about causation, based upon a *proper* differential diagnosis, is sufficiently reliable to satisfy *Daubert*.” *Glastetter*, 252 F.3d at 989 (emphasis added). A *proper* differential diagnosis is “presumptively admissible.” And Plaintiffs avoid mentioning the fact that in *Glastetter*, the Eighth Circuit *affirmed* the district court’s exclusion of an expert’s testimony because his differential etiology, as here, “lacked a proper basis for ‘ruling in’” the defendant’s drug as the cause of the plaintiff’s medical condition. *Id.* In turn, that failure resulted from the underlying scientific reports, which were “not scientifically valid proof of causation” because they “ma[de] little attempt to screen out alternative causes for a patient’s condition.” *Id.* at 989–90.

Plaintiffs' reliance on *Bonner* is again misplaced. (Doc. #70 at 24.) There, the Court noted that a differential diagnosis could be admissible when it identified "the most probable cause" of a condition (which Dr. Hu fails to do here), but held that a differential diagnosis should be excluded if scientifically invalid (as is Dr. Hu's). *Id.* While "[a]ll possible causes . . . need not be eliminated before an expert's testimony will be admitted," even Plaintiffs' own cases recognize "[o]bvious alternative causes need to be ruled out." *McMunn v. Babcock & Wilcox Power Generation Grp., Inc.*, No. 2:10CV143, 2014 WL 814878, at *15 (W.D. Pa. Feb. 27, 2014); *see also Marmo*, 457 F.3d at 758 (excluding an expert for not examining the plaintiff, inquiring about other toxic exposures, or excluding "confounding factors, which 'leaves open the possibility of competing causes of the disease' and raises questions about the competency of expert testimony"); *Kirk v. Schaeffler Grp. USA, Inc.*, 887 F.3d 376, 392 (8th Cir. 2018) ("When an expert's differential analysis fails to rule in exposure to the alleged cause at issue (general causation) and fails to rule out other possible causes, the specific causation opinion is not sufficiently reliable and should be excluded"); *Lauzon v. Senco Prod., Inc.*, 270 F.3d 681, 693 (8th Cir. 2001) (same); *Glastetter*, 252 F.3d at 989 ("In performing a differential diagnosis, a physician begins by 'ruling in' all scientifically plausible causes of the plaintiff's injury. The physician then 'rules out' the least plausible causes of injury *until the most likely cause remains*" (emphasis added)).

Here, too, Dr. Hu's differential etiology must be excluded because he failed to consider and rule out obvious alternative causes of the Plaintiffs' cancers—such as Mr. Hines' repeated exposures to pesticides and herbicides as an exterminator or Mr. Koterba's 45-year pack-a-day smoking history. (Doc. #52 at 17–19.) His failure to look for or consider other possible causes is even more concerning in light of his testimony that the cancers in this case have unknown causes, and the fact there is no epidemiology to support his opinion that Plaintiffs' doses caused their

cancer. *See Bland v. Verizon Wireless, (VAW) L.L.C.*, 538 F.3d 893 (8th Cir. 2008) (excluding an expert for admitting the cause of exercise-induced asthma is unknown and failing to investigate other possible causes).

At bottom, the Eighth Circuit’s decision in the *Baycol* litigation applies with full force here: “This case is not, as [Plaintiff] suggests, like *Bonner*, where there are ‘questions of conflicting’ expert testimony. Rather, it is a case in which [Plaintiff] failed to put forth competent evidence with which to create a conflict. Without competent evidence on both sides, there can be no ‘battle of the experts’ in which a fact-finder could weigh competing claims. Simply put, this case presents us with an expert opinion based on conclusory statements, weak scientific evidence, and temporal proximity in the face of alternative explanations.” *In re Baycol Prod. Litig.*, 596 F.3d 884, 892 (8th Cir. 2010) (citations omitted). Much like the expert in *Baycol*, Dr. Hu’s “opinion on causation simply lacks the factual basis to rise above the level of speculation.” *Id.*

H. Ultimately, Dr. Hu Remains Unqualified to Opine on Specific Causation.

Plaintiffs do not refute critical problems with Dr. Hu’s qualifications for his opinions here. Defendants challenge the qualifications of Dr. Hu to testify to specific causation in this case because he lacks the relevant “knowledge, skill, experience, training, or education,” and failed to grasp basic concepts in the field. (Doc. #52 at 24–27.) Plaintiffs do not contest the fact Dr. Hu himself admitted he was not an expert in health physics, radiation sources, calculating risk from doses, or oncology, and has never published peer-reviewed articles on the health effects of radiation. (*Id.* at 24.) His curriculum vitae makes no mention of radiation. (*Id.*)

As a result, Dr. Hu does not even know the terms necessary to perform the analysis he claims he performed. (Doc. #52 at 25–26). He does not know how to describe the doses Dr. Clark calculated—on which his opinions necessarily rely. (*Id.*) Despite rendering an opinion that the doses in this case caused these Plaintiffs’ cancer, he did not know the radiation doses associated

with everyday exposures to natural background radiation (360 millirem) or the current epidemiological threshold of exposure associated with cancer causation (5,000 millirem⁶). (*Id.*)

Faced with Dr. Hu’s lack of qualifications and his admissions, Plaintiffs are left misrepresenting his testifying history to the Court to give the appearance of qualification. To Defendants’ knowledge, no Court has ruled on Dr. Hu’s qualifications for giving a specific causation opinion on ionizing radiation’s ability to cause a cancer in a plaintiff, which is the issue here. In *McMunn*, a case Plaintiffs cite, Dr. Hu—perhaps in acknowledgement of his own limitations—did not opine on specific causation. (Doc. #70 at 25, citing *McMunn*, No. 2:10CV143, 2014 WL 814878, at *9.)

The Eighth Circuit has “repeatedly upheld the exclusion or reversed the admission of expert design testimony that went beyond the expert’s expertise.” *Am. Auto. Ins. Co. v. Omega Flex, Inc.*, 783 F.3d 720, 724 (8th Cir. 2015) (collecting cases); *Smith v. Rasmussen*, 249 F.3d 755, 759 (8th Cir. 2001) (collecting different cases). After all, “it is the responsibility of the trial judge to determine whether a particular expert has sufficient specialized knowledge to assist jurors in deciding the specific issues in the case.” *Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715 (8th Cir. 2001) (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 156 (1999)). Based solely on his lack of qualifications in the highly complex and narrow field of ionizing radiation’s ability to cause cancer, Dr. Hu’s testimony should be excluded.

IV. CONCLUSION

For these reasons, Dr. Hu’s proffered expert opinions do not meet the requirements for admissibility under Federal Rule of Evidence 702 or *Daubert*. Therefore, Mallinckrodt and Cotter respectfully request this Court enter an Order excluding his opinions and testimony.

⁶ See Doc. #52-9, Mettler-Royal March 17, 2020 Report, p. 1.

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Respectfully submitted,

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